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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,257	02/13/2006	Jung-Keun Kim	1222003USA	9671
JHK Law P.O. Box 1078 La Canada, CA 91012-1078			EXAMINER ISSAC, ROY P	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/568,257

Applicant(s)

KIM ET AL.

Examiner

Roy P. Issac

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/13/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

This application is a 371 of PCT/KR04/02255 filed 09/06/2004 and claims priority to foreign application KOREA 10-2003-0062418 filed 09/06/2003.

Certified copy of the foreign application in Korean is received. No translation is received.

Claims 1-5 are currently pending and are examined on the merits herein.

Claim Objections

Claims 4 and 5 are objected to because of the following informalities: The phrase "any one" is misspelled as "anyone". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating arthritis, does not reasonably provide enablement for the ***prevention*** of arthritis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant application relates to the use of notoginseng radix for the treatment and prevention of arthritis.

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.D. or equivalent advanced degree.

The breadth of the claims:

The claims of the instant application are deemed very broad since it encompasses the treatment and prevention of any type of arthritis.

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The amount of direction or guidance presented and the presence or absence of working examples:

Arthritis is an omnibus term that encompasses several melodies that include osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, Crohn's syndrome, neurogenic arthropathy, and infectious arthritis, diseases with diverse etiology. Rheumatoid arthritis is a chronic syndrome whose cause is unknown and a genetic predisposition is identified. (Merck Manual of Diagnostics, 17th Edition, 1999, Pages 406-423 and 445-459; Page 416, Column 1, Paragraph 3; PTO-892, Cited by the examiner). In view of the genetic predisposition, it is highly unlikely that a drug can prevent the development of rheumatoid arthritis. Osteoarthritis is the other major class of arthritis that has multiple causes. Osteoarthritis is classified into two categories, primary and secondary. Primary osteoarthritis generally have unknown etiology while secondary osteopathy appears to result from conditions that change the microenvironment of the chondrocyte. (Page 449, Column 1, titled "Classification"). Infectious arthritis, on the other hand, can be caused by infections from a variety of pathogens including, Staphylococcus aureus, Streptococci, Enterobacter, Psuedomonas aeruginosa and Seeatia marcescens. (Page 455, Column 1, Section titled "Etiology"). Infectious arthritis is generally treated with antibiotics (Page 458, Column 2), while rheumatoid arthritis is treated with anti-inflammatory drugs and salicylates. (Page 419, Column 1, Section titled "Treatment"). In view of the variety of pathogens that cause infectious arthritis, one of skill in the art will view it as highly unlikely that

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infections from all such pathogens can be prevented with the administration of any drugs.

The specification does not provide any examples of the prevention of arthritis. The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredictable and undeveloped art. See MPEP § 2164.

The predictability or lack thereof in the art: The instant claimed invention is highly *unpredictable* as discussed below:

Prevention of arthritis is not the same as the treatment of a disease condition. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms?

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3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many of the therapies that are useful for treating a disease are not useful preventing the disease. For example, antibiotics, chemotherapeutics and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer. Thus, it is highly unlikely that arthritis can be prevented by the administration of the compositions of the instant application.

The quantity of experimentation necessary:

In order to determine whether the claimed method can prevent arthritis one of ordinary skill in the art will need to answer the questions posed above, which will require significant intellectual and financial input, and an effort that will be collaborative in nature with clinical physicians, organic chemists and biochemists involved, resulting in enormous burden on one of skill in the art to practice the invention as claimed.

Thus, the specification fails to provide clear and convincing evidence in sufficient support for the prevention of arthritis as recited in the instant claims.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful

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conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et. al. (CN 14188690A; Derwent Abstract).

Lin et. al. discloses an extract of the root of Notoginseng. The extraction is prepared by ethyl alcohol and used for tablets and capsules. The recitations, “for preventing and treating arthritis”, and “health food composition” are considered intended use of the extract. Note that it is well settled that “intended use” of a composition or product, e.g., “treating arthritis”, will not further limit

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claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. As such, claims 1-5 are anticipated by Lin et. al.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui et. al. (CN 1348796A; Derwent Abstract; PTO-892, Cited by the examiner).

Cui et. al. discloses a medicinal composition for treating ache comprising extract of radix notoginseng. The extraction was performed by ethyl alcohol. As noted above, the recitations, "for preventing and treating arthritis", and "health food composition" are considered intended use of the extract. As such, claims 1-5 are anticipated by Cui et. al.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et. al. (U.S. Patent NO. 4,755,504; PTO-892, Cited by the examiner).

Liu et. al. discloses a pharmaceutical compositions containing saponin and quercetin derived from Tienchi for the treatment of circulatory disease and as health food. The ingredients are derived from the root Tienchi. Tienchi is the Chinese name for Panax Notoginseng. (Column 1, lines 12-19). A method for extracting Tienchi roots using ethanol is disclosed. (Example 1, Column 3). As noted above, the recitations, "for preventing and treating arthritis", and "health food composition" are considered intended use of the extract. As such, claims 1-5 are anticipated by Liu et. al.

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No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623


S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623